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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,122	CHALIFOUR ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/5/01 & 2/14/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,29,32 and 34-38* is/are pending in the application.

4a) Of the above claim(s) *9-19,22,34-36 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,20,21,29,32 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/4/03*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *3/17/05* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-22, 29, 32 and 34-38 are pending.

The Applicants' preliminary amendment filed 11/5/01 which cancels claims 23-28, 30-31 and 33, amends claims 1, 7-8, 15, 18-22, 32 and 34-36, and add claims 37-38 has been entered. Also, the applicants' request (filed 2/14/05) for extension of time five months has been entered.

Election/restriction

Applicants' election (filed 2/14/05) of Group I, claims 1-8, 20-22, 29 and 32 with traversal for patent examination is acknowledged. The traverse is on the grounds that (i) all claims should be considered as being directed to a single invention and that Example 1 of WO 9721728 (Nordstedt et al.) does not explicitly teach Aβ-peptide comprise D-amino acid residue(s), and thus, 9721728 patent cannot be considered as the prior art over the current invention, and (ii) as the claimed composition (peptide) is novel and inventive, the Groups II, III, and IV should be rejoined in this application for examination.

Applicants' arguments have been fully considered but they are unpersuasive because the 97/21728 patent abstract set forth that the invention relates to peptide compound of formula I or II which comprises D-amino acids, and the patent claims 1-2 especially disclose that the amino acids of the peptide compound are **all** D-isomers or L-isomers. Because "KLVFF" of Example 1 reads on the formula I of claim 1, the all residues of KLVFF are in D-configuration. In addition, Example 5 sets forth that D-pentapeptide (KLVFF), i.e., the amino acids of "KLVFF" peptide are all in D-configuration. Thus, the current application is not novel and/or lacks inventive step over WO 97/21728. The claimed composition does not constitute a special technical feature

linking all claims as a single contribute over the art. Hence, holding of lack of unity is deemed proper. Groups I to IV therefore should not be rejoined and examined together. Hence, the requirement is still deemed proper and is therefore made FINAL.

Note that the new claim 37 is drawn to the invention of Group I. Yet. New claim 38 is not. Claims 9-19, 34-36 and 38 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

In addition, please note that because claim 22 does not depend from any claims of the elected Group I but rather depends from claim 9 of Group II. On communication with Applicants' representative Susan Michaud on March 17, 2005, applicants have been notified that Examiner will examine all claims of Group I but not claim 22 which is drawn to the non-elected Group II invention (see the Interview Summary). Thus, Claims 1-8, 20-21, 29, 32 and 37 are examined in this Office action.

IDS

The references cited in the information disclosure statements (IDS) submitted 4 February 2004 have been placed in the file. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

The following paragraph before the "*Background of the Invention" Description*" paragraph:

"This application is a 371 of PCT/CA00/00515 filed 4 May 2000".

On page 3, line 18, "IAPP" should be spelled out in full for the first instance of use.

In claim 1 "Xaa1-Xaa2-Xaa3-Xaa4 **I** " is objected to because "**I**" should be clearly set froth to be the "Formula I". Also, in claim 1, "all-[D] peptide" should be spelled out; e.g., "peptide of all D-amino acids or all D-stereoisomer of amino acids".

In claim 6, "all-[D] isomer peptide" should be changed to "peptide consisting of all D-amino acids".

In claim 37, "as set forth in SEQ ID NO:3" is advised to be changed to "of SEQ ID NO:3".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 20-21, 29, 32 and 37 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and the dependent claims thereto and claim 29 are drawn to (i) a peptideomimetic composition which is non-peptide chemical compound or any molecule that mimics the biological action of a peptide; (ii) *retro isomer* of the claimed peptide (according to the definition on page 10, the *retro isomer* thereof refers to reversal of the peptide backbone direction); and (iii) *retro-inverso isomer* of the claimed peptide (according to the definition on

page 10, the *retro-inverso isomer* thereof refers to reversal of both the peptide backbone direction and amino acid chirality (stereoisomerism)). The recited peptidomimetic molecule broadly encompasses organic or even inorganic compounds, e.g., vanadium compound is a peptide hormone insulin mimetic (see Thompson, K. H. et al. (1999) *Chem. Rev.* Vol. 99, pages 2561-2571). The specification does not describe how to make and use the peptidomimetic molecules and their activity, e.g., antifibrillogenic activity or inhibiting amyloidosis. Also the specification dose teach or/and provide working examples for the *retro isomer* and the *retro-inverso isomer* of the claimed peptide having antifibrillogenic activity of the Formula I peptide.

Without a statement regarding structural characteristics of the functional peptidomimetic, *retro isomer* or/and the *retro-inverso isomer* of the claimed peptide, one skilled in the art cannot know the metes and bounds of the claimed composition; and thus, one skilled in the art is unable to practice the claimed invention so as to have the antifibrillogenic activity of them. There are no structural parameters for the claimed peptidomimetic, *retro isomer* and the *retro-inverso isomer*, and therefore the claims lacks written description.

Claim Rejections - 35 USC § 112, the second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-8, 20-21, 29, 32 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "isomer thereof"; it is not apparent as to whether or not the isomer refers to (i) peptide comprising D- or L-stereoisomers, i.e., D-form amino acid residues, or (ii) a peptide isomer (e.g., a peptide having amidated at C-terminus *versus* non-modified peptide thereof). The specification does not define the peptide isomer thereof. Nnote that the "isomer thereof" recited in the claim reads on the peptide isomer. See also claim 29. Also, claim 1 is indefinite in "peptidedomimetic" because the specification does not define it; does it refer to non-peptide compound which functionally or/and structurally mimics the claimed peptide compound? Does it encompass inorganic or/and organic compounds that mimic activity of the peptide? The dependent claims are also rejected.

Claim 7 is indefinite because the peptides of SEQ ID NO:5, SEQ IDNO:13 and SEQ ID NOs: 23-24 do not read on the formula I of claim 1, i.e., these sequences do not antecedent basis in claim 1 from which claim 7 depneds5.

Claim 20 is unclear in the recitation "in association with" because it ambiguously refers to that the pharmaceutically acceptable carrier may not be a component of the claimed composition but rather a separate reagent form the composition thereof, i.e., the carrier is not formulated with the peptide in the claimed composition. See also claims 21-22.

Claim 29 is indefinite because "IAPP" is unclear; does it refer to tetrapeptide "Ile-Ala-Pro-Pro" (see page 8, line 12), or, (islet) amyloid polypeptide (see page 3, line 16)? The specification is silent in this regard. Claim 29 is also indefinite in that there is no "SEQ ID NO:_" set forth for IAPP (given that it is the islet amyloid polypeptide) or for protease resistant prion protein, because without the sequence identifier (SEQ ID NO:_), one cannot identify or determine β-sheet region(s) in the polypeptide/protein thereof.

Claim 32 is indefinite as being depending from canceled claim 31. For the examination purpose, claim 32 is taken to depend from claim 29.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5, 7 and 20-21 are rejected under 35 U.S.C. 102 (b) as being anticipated by Rich, D. et al. (WO 9910374).

In the patent claims 1-5 and Example 4, Rich et al. disclose conjugate of β-amyloid-binding peptide with cyclosporin (CsA) wherein the β-amyloid-binding peptide consists of "KLVFF" (see page 94) and wherein the CsA portion comprises at least two D-amino acids. The Rich's conjugate is an isomeric form of the instant compound shown in Formula I, which anticipates the instant claims 1 and 3.

In the Rich's conjugate compound, "X'" moiety is leucinyl residue (hydrophobic amino acid) corresponding to the instant "Xaa2", which anticipates the instant claim 2.

Since the above "KLVFF" residues are L-form amino acids, the Rich's compound meets the limitation of the instant claim 5.

In Example 5 (page 94), Rich et al. teach an antifibrillogenic agent (i.e., the conjugate compound) of the amino acid sequence of "KLVFF-NH_2", which reads on the instant SEQ ID NO:16 and thus anticipates the instant claim 7. Note that claim 7 depends from claim 1 which sets forth an antifibrillogenic agent comprising the *peptide*, and claim 7 further sets forth the limitation to the said *peptide*; thus, the Rich's conjugate comprising the peptide of sequence "KLVFF-NH_2" meets the claim 7 limitation that the peptide is the SEQ ID NO:16.

In the patent claim 8, Rich et al. teach a pharmaceutical composition comprising the said conjugate compound formulated with pharmaceutically acceptable carrier, which anticipates the instant claims 20-21.

Claims 29 and 32 are rejected under 35 U.S.C. 102 (b) as being anticipated by Kayed, R. et al. (*J. Mol. Boil.* (1999, April) 287, 781-796).

Kayed et al. teach an islet amyloid peptide ("IAPP") which comprises β-sheet content (see abstract, page 783, the right column, the 1st paragraph, and page 791, the right column), and that the IAPP molecule is useful for inhibiting amyloid protein aggregation and thus has cytoprotection function (see page 793, the right column). The Kayed's teachings anticipate the instant claim 29.

In Figures 2-6, Kayed et al. teach that the said peptide is dissolved in 10 mM phosphate buffer (pH7.4) which is considered to be a pharmaceutically acceptable carrier and the solution comprising the peptide and carrier thereof is considered to be a pharmaceutical composition. The Kayed et al. teaching anticipates the instant claim 32.

Claim 29 is rejected under 35 U.S.C. 102 (b) as being anticipated by Moriarty, D. F. et al. (*Biochemistry* (1999, February) 38, 1811-1818).

Moriarty et al. teach a mutant islet amyloid polypeptide ("IAPP") which comprises a β-sheet region (amino acid residues 20-29) (see abstract and Figure 1) wherein a proline substitution of any residue in the region inhibits aggregation and amyloid formation (see abstract), i.e., inhibits amyloidosis. The Moriarty's teaching anticipates the instant claim 29.

Claims 29 and 32 are rejected under 35 U.S.C. 102 (b) as being anticipated by Pan, K-.M. et al. (*Proc. Natl. Acad. Sci. U S A.* (1993) 90, 10962-10966) as is evidenced by the known fact that prion protein (PrP^{sc}) is a protease-resistant isoform of prion protein (Wong, B.-S. et al. (2001, May) *J. Phathol.* 194, 9-14).

Pan et al. teach a scrapie prion protein (PrP^{sc}) which has high β-sheet content in region of amino acid residues 27-30 (see abstract), and teach that secondary structure transition from β-sheet to α-helix is useful for treating amyloid plaques cause by the scrapie prion protein (an amyloidosis state) (see page 10962, the right column, and page 10965). The Pan's teachings anticipate the instant claim 29.

In "*Materials and Methods*" section, Pan et al. teach that the prion protein, e.g., Prp 27-30 peptide (see page 10963, the left column, the 4th paragraph), is dissolved in sodium phosphate buffer (PBSZ) which is considered to be a pharmaceutically acceptable carrier and the solution comprising the Prp 27-30 peptide and the carrier thereof is considered to be a pharmaceutical composition. The Pan's teaching thus anticipates the instant claim 32.

Claims 1 and 20-21 are rejected under 35 U.S.C. 102 (e) as being anticipated by Green, A. M. et al. (US Pat. No. 6670399).

In Example 2 (column 24), Green et al teach a compound which is peptidomimetic to the instant peptide compound of claim 1, i.e., a functional mimetic because the Green's compound is capable of inhibiting cerebral amyloid angiopathy (CAA), which is an amyloidosis disease state. Thus, the Green' teaching anticipate the instant claim 1. Note that the Green patent is applicable because the instant claim 1 as written is drawn to a functional peptidomimetic of the claimed peptide of the Formula I.

On column 22 and the patent claim 1, Green et al. further teach a pharmaceutical composition comprising the said compound and a pharmaceutically acceptable carrier (see column 20, lines 39-47) for treating the above mentioned disease state, as applied to the instant claims 20-21.

Claims 1-4, 6-7 and 20-21 are rejected under 35 U.S.C. 102 (e) as being anticipated by Nordstedt, C. et al. (US Pat. No. 6331440).

In Example 5, Nordstedt et al. disclose a peptide compound comprising "KLVFF" which reads on the instant Formula I of claim 1, wherein all amino acid residues are D-forms (see the patent claim 7). The Nordstedt's disclosure anticipates the instant claims 1, 3-4 and 6.

In the above Nordstedt's peptide, "L" (leucine, equivalent to the instant "Xaa2") is hydrophobic amino acid "Leu" residue, which anticipates the instant claim 2.

The Nordstedt's peptide "KLVFF" reads on the instant SEQ ID NO:8, which anticipates the instant claim 7.

In Example 5, the peptide is dissolved in a HEPES buffer solution (see column 6, lines 48-52) wherein the buffer is considered to be pharmaceutical acceptable carrier, which anticipates the instant claims 20-21.

Claims 1-7, 20-21 and 37 are rejected under 35 U.S.C. 102 (e) as being anticipated by Findels et al. (US Pat. No. 66303567).

In the patent claim 95, Findels et al. teach a peptide compound of one of the following sequences: SEQ ID NO:28 (HQKLVFFA), SEQ ID NO:29 (HQKLVFF), SEQ ID NO:30 (QKLVFFA), SEQ ID NO:31(QKLVFF), SEQ ID NO:32 (KLVFFA) and SEQ ID NO:46 (KLVFF), all which read on the instant formula I. And, Findels et al. further teach that at least one L-amino acid of the above sequences is substitutes with a D-amino acid. The Findels' teachings anticipate the instant claims 1, 3-5 and 7.

In the above peptide of SEQ IF NO:46, "L" (leucine) corresponding to the instant "Xaa2" is a hydrophobic residue, which anticipate the instant claim 2.

In the patent claim 1, Findels et al. teach an β-amyloid modulator (inhibiting β-amyloid polypeptide aggregation) which consists entirely of D-amino acid residues and 3-5 residues. Further, in the patent claim 20, Findels et al. teach the β-amyloid modulator compound comprising the formula; this formula meets the all structural characteristics of the instant Formula I (note that the "KLVFF" of SEQ ID NO:46 reads on this formula). The Findels' patent anticipates the instant claim 6.

The Findels' peptide "KLVFF" reads on the formula set forth in the patent claim 123 *wherein* Findels et al. teach a pharmaceutical composition comprising the formula thereof and a pharmaceutically acceptable carrier, which anticipates the instant claims 20-21.

Since the Findels' SEQ ID NO:32 (KLVFFA) reads on the instant SEQ ID NO:3, the Findels patent anticipates the instant claims 7 and 37.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moriarty, D. F. et al. (*Biochemistry* (1999, February) 38, 1811-1818) taken with Findels, M. A. et al. (US Pat. No.5854204) (from the applicants' IDS filed 2/4/2004).

Moriarty et al. teach a mutant islet amyloid polypeptide ("IAPP") which comprises a β-sheet region (amino acid residues 20-29) (see abstract and Figure 1) wherein a proline substitution of any residue in the region inhibits aggregation and amyloid formation (see abstract), i.e., inhibits amyloidosis, which is applied to the instant claim 29.

On column 2, line 65 to column 3, line 14, Findels et al. teach a pharmaceutical composition comprising the IAPP molecule, and on column 5, lines 45-49, teach pharmaceutical acceptable carrier for the composition. Also, Findels et al. teach that amino acid residues 20-29 of the IAPP form amyloid-like fibril, i.e., β-strand (see column 43, lines 55-67). The Findels' teachings are applied to the instant claim 32.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the said IAPP with the pharmaceutical carrier so as to make the pharmaceutical composition. One skilled in the art would have been motivated to do this because the composition is useful for inhibiting aggregation of natural amyloidogenic proteins and peptides, and thus for treating amyloidosis disease state, as taught by Findels et al. (see column 3, lines 1-18, and column 6, lines 22-48, respectively).

Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting

Claims 1 and 6-8 of this application conflict with claim 27 Application No.10345855. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR

3.73(b).

Claims 1 and 6-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 27 of 09915092. This is a provisional obviousness type double patenting rejection because the conflicting claims have not in fact been patented.

Although the conflicting claims are not identical, they are not patentable distinct from each other because of the reasons set forth below.

Claim 27 of 09915092 discloses a peptide compound comprising "dLys-dLeu-dVal-dPhe-dPhe-dAla-OH (SEQ ID NO:28) which reads on the instant claim 1 formula I. Note that preamble "for inhibiting amyloidosis" is an inherent property of the claimed composition; and thus, the 09915092 compound inherently has the property thereof.

The SEQ ID NO:28 sequence reads on the instant SEQ ID NO:2, which is the subject matter set forth in the instant claims 7 and 8.

In the SEQ ID NO:28 peptide, all the amino acid residues are in D-forms, which is the subject matter of the instant claim 6.

Thus, the claims and the instant claims are not patentably distinct from each other.

Prior Art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

(1) Findels, M. A. et al. (US Pat. No.5985242) teach peptide compounds which are derived from β-amyloid comprises D-amino acid residue for treating amyloidogenic disease and pharmaceutical composition comprising the compound thereof.

(2) Findels, M. A. et al. (US Pat. No.6831066) teach peptide compounds which derived from β-amyloid comprises D-amino acid residue for treating amyloidogenic disease and pharmaceutical composition comprising the compound thereof.

(3) Findels, M. A. et al. (US Pat. No.6277826) teach peptide compounds which are derived from β-amyloid comprises D-amino acid residue for treating amyloidogenic disease and pharmaceutical composition comprising the compound thereof.

(4) Findels, M. A. et al. (US Pat. No.6610658) teach peptide compounds which are derived from β-amyloid comprises D-amino acid residue for treating amyloidogenic disease and pharmaceutical composition comprising the compound thereof.

(5) Findels, M. A. et al. (US Pat. No.6689752) teach peptide compounds which are derived from β-amyloid comprises D-amino acid residue for treating amyloidogenic disease and pharmaceutical composition comprising the compound thereof.

(6) Roberts, E. (US Pat. No. 5470951) teach a peptide compound comprising the motif "KLVFF" (see the patent claims 1-4). The said compounds are useful in treating amyloid β protein aggregation –associated disease states. Yet, Roberts does not teach the compound comprises D-form amino acid(s).

(7) Gasset, M. et al. (*Proc. Natl. Acad. Sci. U S A.* (1993) 90, 1-5) teach characterization of β- beta-sheets features of scrapie prion proteins and their potential role in amyloid aggregation.

(8) Nordstedt, C. et al. (WO 9721728) teach a peptide compound of Formula I wherein "Y" is Lys (claim 4), "Z" is Phe (claim 5), and "X" is "Val-Val" (claim 7) which is a *functional* isomeric form of the instant Formula I (see patent claims 1-7). In the patent claims 2 and 19,

Nordstedt et al. teach that the peptide is useful for inhibiting aggregation of amyloid β peptides (claim 2) and treating amyloidosis (claim 19). The Nordstedt's patent claim 1 sets forth that all amino acids are in D-forms. Also, Nordstedt et al. teach that all amino acids of the formula I are in D-configuration. Further, Nordstedt et al. teach "KLVFF" peptide wherein all the residues are D-amino acids (claim 7) and a pharmaceutical composition comprising the Formula I peptide for treating amyloidosis, wherein the peptide is formulated with a carrier (see page 8, lines 25-29).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weber, Jon, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel Wei Liu, Ph.D.
Art Unit 1653, Examiner

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER